

**REMARKS**

Claims 73-75, 103-105, 108, and 122-133 were pending in the present application. By virtue of this response, claims 75, 103-105, 108, and 122-133 are cancelled and claim 73 is amended. Accordingly, claims 73-74 are currently under consideration. Allowance of the pending claims is respectfully requested.

**Request for Interview**

In the interest of expediting resolution of any remaining issues in this case, Applicant respectfully requests the courtesy of a telephonic interview with the Examiner regarding this application prior to issuance of any Office Action on the merits following submission of this Amendment and accompanying Request for Continued Examination. The Examiner is invited to telephone the undersigned at the number given below to schedule the interview at the Examiner's earliest convenience.

**Priority**

By submission of the Supplemental Application Data Sheet filed herewith, this application is amended to claim the priority benefit of additional prior patent applications. As indicated in the accompanying Supplemental Application Data Sheet, this application is the National Stage of International Application No. PCT/US98/13272, filed June 26, 1998, which: (a) claims the priority benefit of U.S. Provisional Application No. 60/051,021, filed June 27, 1997; (b) is a continuation-in-part of U.S. Application No. 08/926,155, filed September 9, 1997; and (c) is a continuation-in-part of U.S. Application No. 08/720,756, filed October 1, 1996, which is a continuation-in-part of U.S. Application No. 08/412,726, filed March 29, 1995, which is a divisional of U.S. Application No. 08/023,698, filed February 22, 1993.

In the Office Action mailed February 10, 2004, the Examiner asserted that claiming the priority benefit of some of the above-listed prior applications was improper. Applicant, however, respectfully submits that the present application is entitled to claim the priority benefit of each of the applications indicated above and in the Supplemental Application Disclosure Statement filed

herewith under 35 U.S.C. § 119(e) or 35 U.S.C. §§ 120 and 365(c) and 37 C.F.R. §§ 1.78(a). With respect to the addition of the claim to the priority benefit of U.S. Application No. 08/720,756, filed October 1, 1996, Applicant notes that the priority claim is proper since U.S. Application No. 08/720,756 was copending on the international filing date of the present national stage application, June 26, 1998 (see MPEP § 1893.03(c)(III)). It is respectfully submitted that Applicant is entitled to the claim of priority benefit back to February 22, 1993.

### **Specification**

The “Related Applications” section of the application which was previously submitted in an amendment on August 6, 2004, has now been deleted. No new matter has been added.

### **Claim Amendments**

Claim 73 is amended to recite that the albumin is crosslinked by disulfide bonds. Support for this amendment is found, e.g., at page 22, lines 17-18, at page 46, line 26, to page 47, line 9, and at page 53, lines 8-13 of the application as originally filed on June 26, 1998. Also, claim 73 is further amended to delete the word “amorphous” from the claim. No new matter is added by the amendment of claim 73.

Claims 75, 103-105, 108, and 122-133 are cancelled.

With respect to all amendments and cancelled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and, moreover, has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation, continuation-in-part, and/or divisional applications.

**Claim Rejections under 35 U.S.C. § 102**

Claims 73, 103, 108 and 122-132 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Violante (U.S. Patent No. 5,741,522). By cancellation of claims 103, 108 and 122-132, this rejection has been rendered moot with respect to those claims. Applicant respectfully traverses this rejection with respect to claim 73.

Claim 73, as amended, is directed to an article of manufacture comprising a dry powder or liquid formulation of water insoluble drug and at least one protein, wherein the formulation comprises a solid core of water insoluble drug nanoparticles coated with the protein, and wherein the protein is albumin and the albumin is crosslinked by disulfide bonds.

To anticipate a claim, a prior art reference must teach or suggest each and every limitation of the claim. Applicant respectfully submits that Violante does not anticipate claim 73, because Violante fails to disclose or suggest all elements of claims 73. Violante fails to disclose or suggest an article of manufacture comprising a dry powder or liquid formulation of water insoluble drug and at least one protein, wherein the formulation comprises a solid core of water insoluble drug nanoparticles coated with the protein, and wherein the protein is albumin and the albumin is crosslinked by disulfide bonds.

Since Violante neither teaches nor suggests each and every element of claim 73, Applicant respectfully requests that the rejection of claim 73 under 35 U.S.C. § 102(e) be withdrawn.

**Claims Rejections under 35 U.S.C. § 103**

Claims 73, 74, 104 and 133: Claims 73, 74, 104 and 133 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Violante (U.S. Patent No. 5,741,522) in view of Unger (U.S. Patent No. 6,143,276). Claims 104 and 133 are cancelled by this amendment, thereby rendering the rejection moot with respect to claim 104. However, Applicant respectfully traverses this rejection with respect to claims 73 and 74.

As noted above, claim 73, as amended, is directed to a article of manufacture comprising a dry powder or liquid formulation of water insoluble drug and at least one protein, wherein the formulation comprises a solid core of water insoluble drug nanoparticles coated with the protein, and wherein the protein is albumin and the albumin is crosslinked by disulfide bonds. In dependent claim 74, the drug is a taxane.

To establish a prima facie case of obviousness, the prior art references must teach or suggest each and every claim limitation. Violante, in combination with Unger, does not teach or suggest all elements of claims 73 and 74. Violante, both alone and in combination with Unger, fails to disclose or suggest an article of manufacture comprising a dry powder or liquid formulation of water insoluble drug and at least one protein, wherein the formulation comprises a solid core of water insoluble drug nanoparticles coated with the protein, and wherein the protein is albumin and the albumin is crosslinked by disulfide bonds.

In addition, it is respectfully submitted that the rejection of claims 73 and 74 is rendered moot by the amendment of this application to include additional priority claims. As noted above, this application now claims the priority benefit of U.S. Application No. 08/023,698, filed February 22, 1993, as well as of other applications. As a result, Unger, which was filed March 21, 1997, does not constitute prior art.

Since Violante, in view of Unger, does not teach or suggest each and every element of claims 73 and 74, and further, since Unger does not constitute prior art, Applicant respectfully requests that the rejection of claims 73 and 74 under 35 U.S.C. § 103(a) be withdrawn.

Claim 105: Claim 105 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Violante (U.S. Patent No. 5,741,522) in view of Unger (U.S. Patent No. 6,143,276), as applied to claims 73, 74, 104 and 133 above, and further in view of Jones (U.S. Patent No. 5,731,355). This rejection has been rendered moot by the cancellation of claim 105.

Claims 73-75, 103-104, 108 and 122-133: Claims 73-75, 103-104, 108 and 122-133 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Desai (U.S. Patent

No. 5,439,686) in view of Westesen (U.S. Patent No. 6,197,349). Applicant assumes for purposes of this response that the Examiner intended to make this rejection under 35 U.S.C. § 103(a), not under 35 U.S.C. § 102(b), since a combination of references was cited in the rejection and the rejection was listed under the “Claim Rejections – 35 USC § 103” heading of the Office Action. If this assumption is incorrect, clarification on the record would be appreciated.

Claims 75, 103-104, 108 and 122-133 are cancelled by virtue of this amendment, thereby rendering the rejection moot with respect to claims 75, 103-104, 108 and 122-133. However, Applicant respectfully traverses this rejection with respect to claims 73 and 74.

It is respectfully submitted that the rejection of claims 73 and 74 over Desai in view of Westesen is rendered moot by the amendment of this application to include additional priority claims. As noted above, this application, as amended, now claims the priority benefit of Desai, filed February 22, 1993, as well as of other applications. Accordingly, neither Desai nor Westesen constitutes prior art.

Since the rejection of claims 73 and 74 over Desai and Westesen is moot in light of the amended priority claims, Applicant respectfully requests that the rejection of claims 73 and 74 over Desai and Westesen be withdrawn.

#### **Claims Rejections under 35 U.S.C. § 112**

Claim 75 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Without acquiescing to the rejection and in the interest of expediting prosecution of the remaining claims, claim 75 has been cancelled, thereby rendering the rejection of claim 75 under 35 U.S.C. § 112 moot.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 420052000126. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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